

AD _____

Award Number: DAMD17-01-1-0628

TITLE: The Effect of a Home-Based Walking Intervention on Quality of Life, Body Composition, and Estrogen Metabolism in Postmenopausal Breast Cancer Survivors

PRINCIPAL INVESTIGATOR: Sara Wilcox, Ph.D.

CONTRACTING ORGANIZATION: University of South Carolina
Columbia, SC 29208

REPORT DATE: September 2005

TYPE OF REPORT: Final

20060315 060

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-09-2005		2. REPORT TYPE Final		3. DATES COVERED (From - To) 1 Sep 2001 – 31 Aug 2005	
4. TITLE AND SUBTITLE The Effect of a Home-Based Walking Intervention on Quality of Life, Body Composition, and Estrogen Metabolism in Postmenopausal Breast Cancer Survivors				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER DAMD17-01-1-0628	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Sara Wilcox, Ph.D. E-mail: SWILCOX@SC.EDU				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of South Carolina Columbia, SC 29208				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Increased incidence of and survival from breast cancer have resulted in growth of the number of women who have survived this disease and are faced with the subsequent consequences of their diagnosis and treatment. Physical activity is a modifiable health behavior that has the potential to address both the emotional and physical needs of women with early stage breast cancer. However, for physical activity to be seen as a viable treatment option, and for a change in routine care to occur, its effectiveness must be determined. Accordingly, the objectives of this pilot study are to; 1) quantify the effect of a 12-week home-based walking intervention on quality of life, body composition, and estrogen metabolism in survivors of breast cancer, and 2) develop and test the feasibility of physical activity intervention materials for future studies in this population. The recruitment of participants began in 4/05 due to challenges in institutional agreements regarding coverage of potential medical expenses incurred by women as a consequence of their participation in this research. Since the resolution of this issue, we have recruited 12 women into the study, and our recruitment efforts are ongoing. Due to the small numbers and ongoing recruitment, analyses have not yet been initiated. We have requested a one-year extension of the project.					
15. SUBJECT TERMS Exercise, physical activity, quality of life, body weight, estrogen metabolism					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 5	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

Table of Contents

Cover.....	
SF 298.....	
Table of Contents.....	
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	5
Reportable Outcomes.....	5
Conclusions.....	5
References.....	5

Introduction

Increased incidence of and survival from breast cancer have resulted in growth of the number of women who have survived this disease and are faced with the subsequent consequences. Diagnosis and treatment of breast cancer are associated with several adverse physical and psychosocial outcomes (e.g., weight gain, reduced physical activity levels, loss of lean body mass, depression, lowered self-esteem). Some of these adverse effects are attenuated after adjuvant treatment ends. However, psychological distress and weight gain may persist, resulting in reduced quality of life and increased risk of recurrence. Physical activity participation may attenuate the adverse effects outlined above and improve hormonal factors that influence breast cancer recurrence (1). Given these benefits, it is remarkable that physical activity programs have not been adapted for breast cancer survivors until very recently. In order for physical activity to be seen as a viable treatment option, and for a change in routine care to occur, its effectiveness must be determined. Accordingly, the objectives of this pilot study are to; 1) quantify the effect of a 12-week home-based walking intervention on quality of life, body composition, and estrogen metabolism in survivors of breast cancer, and 2) develop and test the feasibility of physical activity intervention materials for future studies in this population. We hypothesize that women randomized to the walking intervention will report higher levels of quality of life, experience less weight gain, and have more favorable estrogen metabolite profiles.

Body

DESIGN. Fifty postmenopausal women recently diagnosed with breast cancer will be recruited from the South Carolina Cancer Center (Columbia, SC). Thirty women will be randomized to a 12-week walking intervention and 20 women to a control group. The control group will be offered a walking program following the randomized experiment to allow them benefit from the intervention and improve compliance during the trial. All women will be screened for contraindications to the moderate-intensity walking program (i.e., anemia, immune suppression, extreme fatigue, bone pain, and symptoms of cardiovascular disease and orthopedic problems) and excluded as necessary. The intervention will occur after treatment is completed. Experimental groups will be balanced by stage of breast cancer and treatment type. To date, 12 have been enrolled into the study and randomized (9 to the walking group and 3 to the control group).

INTERVENTION. Participants randomized to the intervention complete a 12-week home-based walking program using the Stanford model developed and refined by King and colleagues (1). Supervised home-based programs are preferred by most adults (5) and have been shown to be safe even in older ages and the obese. To maximize safety, participants are instructed to gradually increase their walking duration and intensity. By the eighth week of the intervention, the goal is to walk for 30-40 minutes, 5 times per week, at a moderate intensity level (i.e., 3-4 mph). Women in the intervention have an initial in-person counseling session with a health educator that will emphasize physical activity safety (i.e., perceived exertion, warm-up, and cool-down). They also receive 5 brief telephone calls by a health educator to monitor participant safety and enhance adherence during the 12-week intervention. Adherence is monitored with self-report logs and pedometers. Dr. Sara Wilcox, a psychologist and Associate Professor in Exercise Science at USC, oversees the intervention.

OUTCOMES. Quality of life is measured with the Medical Outcomes Study SF-36 that evaluates eight domains of life quality (e.g., physical, social, bodily pain, mental health). Changes in body mass and composition are quantified with anthropometric measures and bioelectrical impedance. Estrogen metabolite levels will be measured among half of the overall sample (n=25), or in the number that qualify for this substudy, from spot urine samples in triplicate using the Estramet 2/16 kit (Immuna Care Corp, Bethlehem, PA). To date, no women have qualified for this substudy. Women in the

estrogen sub-study will only be included if they are overweight (i.e., body mass index > 25 kg/m²). The assay is a direct measure of 2-hydroxyestrone and 16alpha-hydroxyestrone. CYP1A2 activity, an enzyme regulating 2-hydroxyestrone formation, will be measured in urine. These markers of estrogen metabolism have been associated with breast cancer risk and physical activity levels. Changes in physical activity are assessed by questionnaire and an accelerometer (2, 4). Outcomes are measured at baseline, 6-, and 12-weeks. Availability of these data allow for examination of the effect of the intervention in returning women toward pre-diagnosis levels of physical and psychosocial health.

SUMMARY. This pilot study evaluates the effectiveness of a generalizable physical activity intervention for improving quality of life and two biologic factors associated with prognosis in postmenopausal breast cancer survivors. These data will provide the necessary quantitative estimates of outcome effect sizes that will be used for submission of a larger-scale proposal to rigorously test the hypotheses outlined above. This work has the potential to add an important new treatment option for the growing population of breast cancer survivors.

Key Research Accomplishments

To date we have enrolled and randomized 12 participants in the study (9 to the walking group and 3 to the control group). Two participants have completed the study. One participant has withdrawn from the study (due to lack of time). Recruitment is ongoing.

Reportable Outcomes

None – recruitment is ongoing

Conclusions

Not yet available – recruitment is ongoing.

References

1. King, A. C., W. L. Haskell, C. B. Taylor, H. C. Kraemer, and R. F. DeBusk. Group- vs home-based exercise training in healthy older men and women. A community-based clinical trial. *Journal of the American Medical Association*. 266:1535-1542, 1991.
2. Matthews, C. E., B. E. Ainsworth, R. W. Thompson, and D. J. Bassett. Sources of variance in daily physical activity levels as measured by an accelerometer. *Medicine & Science in Sports & Exercise*. 34:1376-1381, 2002.
3. Matthews, C. E., S. Wilcox, A. Skiba, S. Heiney, and C. Der Ananian. A Home-Based Walking Intervention Among Breast Cancer Survivors (abstract). In *Era of Hope 2002: Department of Defense Breast Cancer Research Meeting*. Orlando, FL., 2002.
4. Stewart, A. L., K. M. Mills, A. C. King, W. L. Haskell, D. Gillis, and P. L. Ritter. CHAMPS Physical Activity Questionnaire for Older Adults: Outcomes for interventions. *Medicine & Science in Sports & Exercise*. 33:1126-1141, 2001.
5. Wilcox, S., A. C. King, G. S. Brassington, and D. K. Ahn. Physical activity preferences of middle-aged and older adults: A community analysis. *Journal of Aging and Physical Activity*. 7:386-399, 1999.
6. Wilcox, S., C. E. Matthews, and A. Skiba. Adherence To A Home-Based Walking Program In Breast Cancer Survivors: A Pilot Study [abstract]. *Annals of Behavioral Medicine*. 24:S190, 2002.